UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,307	05/25/2001	Lawrence P. Wackett	110.00440102	4705

26813 7590 11/25/2003

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/866,307	WACKETT ET AL.	
	Examin r	Art Unit	
	Richard G Hutson	1652	

--The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

THE REPLY FILED 15 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *30,41,45 and 49*.

   Claim(s) rejected: *25-29,35-40,42-44,46-48 and 50*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *IDS-8/2002*

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit: 1652

Continuation of 2. NOTE: Applicants proposed amendment of claims 25 and 36 to recite "improved ability to degrade atrazine and increased degradation of terbuthylazine" introduces a new issue afterfinal Specifically the recitation "increased degradation of terbuthylazine" is a new issue after final that has not previously been considered.

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicants reply has overcome the objection to the specification regarding Figure 9.

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 25-29, 35-40, 42-44, 46-48 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
This rejection was stated in the previous office action as it applied to previous claims 25-30. In response to this rejection applicants have proposed amendments of claims 25 and 36 and traverse the rejection as it applies to the amended claims .
Applicants continue to traverse the rejection on the basis that applicants claims comply with the written description requirement for those reasons stated in the response of April 28, 2003.
Applicants further submit that the written description requirement is satisfied by the sufficient description of a representative number of species and that the present application teaches seven species having altered catalytic activity for atrazine, six of which also display an increased degradation of terbuthylazine. Applicants submit that the seven species disclosed are representative of the genus as all members have at least 95% identity to SEQ ID NO: 2 and all members must have the specific activity. Applicants arguments continue to not be found persuasive as applicants have not
disclosed any relationship between the defined structural characteristics and the various different functional characteristics such that the claimed genus of methods of use is not defined based on an adequate description of the genus of proteins having the claimed structural and various functional characteristics. As previously stated, it is acknowledged that applicants teach 7 species of proteins (i.e. SEQ ID NOs: 5, 6, and 22-26), however how each of the species relates to the functional characteristics of the proteins of the claimed method is unclear, thus applicants have not adequately described the genus of methods of use of such a genus of atrazine chlorohydrolase enzymes.
Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 25-29, 35-40, 42-44, 46-48 and 50 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a sample comprising an s-triazine-containing compound comprising adding a composition to a sample comprising an s-triazine-containing compound, wherein the composition comprises a protein of SEQ ID NO: 2, 5, 6 or 22-26, does not reasonably provide enablement for any method of treating a sample comprising an s-triazine-containing compound comprising adding a composition to a sample comprising an s-triazine-containing compound, wherein the composition comprises a protein encoded by a nucleic acid which hybridizes under the specified high stringency conditions wherein the protein has a altered catalytic activity relative to the protein of SEQ ID NO: 2, wherein the altered catalytic activity is selected from the group consisting of altered catalytic rate as quantified by kcat and KM , altered substrate range, altered substrate preference, altered activity in aqueous solutions, altered stability in solvents, altered active temperature range, altered salt concentrations for enzymatic activity, altered pH for enzymatic activity and improved activity in a soil environment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
Applicants traverse this rejection on the basis the points, a, b, c and d on page 9 of the previous action (i.e. (A) regions of the protein structure which may be modified without effecting atrazine degrading activity or those regions responsible for such alterations in atrazine catalytic activity selected from the group consisting of altered catalytic rate as quantified by kcat and KM, altered substrate range, altered substrate preference, altered activity in aqueous solutions, altered stability in solvents, altered active temperature range, altered salt concentrations for enzymatic activity, altered pH for enzymatic activity and improved activity in a soil environment ; (B) the general tolerance of atrazine degrading enzymes to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a atrazine degrading enzyme with an expectation of obtaining the desired altered catalytic activity; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful) are not required by the statue and applicants are not aware of case law that includes such requirements.
In response to applicants comments, applicants are reminded that the points (A) through (D) are merely provided as means of providing guidance to enable the claimed methods Thus because of the lack of guidance of the specification, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the atrazine degrading activity while simultaneously altering this activity such as altering the catalytic rate as quantified by kcat and KM, altering the substrate range, altering the substrate preference, altering the activity in aqueous solutions, altering the stability in solvents, altering the active temperature range, altering the salt concentrations for enzymatic activity, altering the pH for enzymatic activity and improving the activity in a soil environment as claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those methods of use of the claimed mutant atrazine degrading enzymes.
As stated previously and repeated by applicants, Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).
Thus, for all of the reasons previously stated, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed method of use of the claimed mutant atrazine degrading enzymes. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those enzymes, for use in the claimed methods, which have the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988)..